UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming

Products Liability Litigation

This Document Relates To:

All Actions

MDL No. 15-2666 (JNE/FLN)

MEMORANDUM IN SUPPORT OF

3M's MOTION TO REMOVE

"CONFIDENTIAL"

DESIGNATION FROM

DOCUMENTS PRODUCED BY

AUGUSTINE

(FILED UNDER SEAL)

INTRODUCTION

Since 2007, Dr. Scott Augustine has engaged in a deliberate and calculated strategy designed to further his own business and financial interests by publicly disparaging the 3MTM Bair HuggerTM patient warming system. Directly and through his many affiliated entities, he has published websites, posted videos, contributed to newspaper articles, written to regulators, and created a national campaign to recruit potential plaintiffs in litigation against 3M and the Bair Hugger system. Augustine has taken his crusade public at every opportunity.

Now that he has been required to produce the documents related to his public efforts disparaging the Bair Hugger system, Augustine claims the documents are somehow "confidential" and cannot be used outside the context of this litigation. Augustine cannot have it both ways. He has not articulated any basis on which the documents should be deemed confidential – he certainly has not treated them as such. On their face, the

documents do not satisfy the requirements for confidential treatment set forth in the Protective Order and Rule 26(c) of the Federal Rules of Civil Procedure.

At bottom, the extent to which Augustine has already made this information available to the public – and actively encouraged public disclosure – belies any expectation of or entitlement to confidentiality. The documents contain information that 3M can use to refute the false and misleading statements that have been made in the public record and to regulatory agencies. It would be contrary to the public interest to prohibit 3M from correcting the damaging – and false – impressions that Augustine has sought to create. Accordingly, 3M requests that the "confidential" designation be lifted from the documents identified on Exhibit A to the Declaration of Monica L. Davies ("Davies Decl."), and that 3M be permitted to use these documents for any business or legal purpose it deems appropriate.¹

BACKGROUND

The documents produced by Augustine, described in more detail in Exhibit A to the Davies Decl., include the following: (1) the litigation guide prepared by Augustine, and communications between him and others (including Plaintiffs' counsel) regarding its preparation, editing, and dissemination; (2) communications regarding the status of early Bair Hugger litigation and how to publicize it; (3) negative publicity regarding the Bair Hugger generated and/or encouraged by Augustine, including public presentations

¹ For purposes of this motion, 3M is seeking de-designation of Augustine's documents only. 3M will bring a similar motion, if necessary, to address Augustine's deposition testimony after his deposition is concluded.

regarding his criticisms of the Bair Hugger system and videos made publicly available via YouTube; (4) communications between Augustine and the FDA regarding Augustine's misleading statements about the Bair Hugger system and his competing HotDog product; (5) data underlying studies relied upon by Augustine and Plaintiffs to support their claims that the Bair Hugger causes surgical site infections; and (6) documents pertaining to the email blast initiated by Augustine in early 2017 falsely claiming that the Bair Hugger system is facing a recall. *See* Davies Decl., Ex. A.

Although these documents cover a variety of topics, the common thread among them is that their information has been deliberately and strategically publicized by Augustine when it serves his purposes. Augustine now seeks to protect these documents as confidential, but is unable to articulate any good faith basis to do so. Indeed, his explanation for why he refuses to lift the confidential designation is his belief that 3M might use his documents or testimony outside the context of this litigation. In other words, Augustine will only agree to lift the "confidential" designation if 3M agrees to treat his documents and testimony as confidential nonetheless. Leaving aside the hypocrisy underlying his position, his fear that this information may finally be publicly aired is not a sufficient basis on which to invoke the protections of confidential treatment. Augustine has repeatedly publicized his false claims about the Bair Hugger system. Having put the story out there, Augustine should not be permitted to close the book now.

A. Augustine Concocted the Bair Hugger Litigation as a Competitive Business Strategy.

Augustine was the original inventor and developer of the Bair Hugger warming blanket. After being forced to leave the company, Augustine developed a new patient warming device with a different design – the "HotDog" – which works much like an electric blanket and warms patients through direct skin contact instead of with warm air. Augustine tried to convince Defendants to buy his new product, claiming that the Bair Hugger system had suddenly become dangerous. *See* Davies Decl., Ex. B. Indeed, Augustine offered to "sell [Defendants] the solution" to his imagined "contamination problem" and declared he had "no doubt that HotDog conductive fabric warming will ultimately replace FAW." *See id.*

When Augustine's efforts to extort Defendants failed, he created a roadmap for plaintiffs' lawyers to sue 3M. Augustine then sought partnerships with law firms to recruit potential plaintiffs and encourage public litigation against 3M:

Scott and I are preparing a detailed guide to suing 3M/Bair Hugger for orthopedic implant infections. It will contain background, summaries of and links to scientific articles, explanations of joint infections, a timeline of 3M's knowledge and failure to warn, discovery suggestions...and a half-dozen other useful things.

We intend to offer it to other plaintiffs' firms around the country who express an interest in jumping on this bandwagon. Our staff is preparing a list of the email addresses of AAJ members who do this work, and we may do an email blast. Communications in the AAJ publications may also be a good idea.

My question: Would you like [Kennedy Hodges] to be the author of this Guide? It would help establish KH as the leader

in this area. Of course, if KH is the listed author, you guys will want to be comfortable with the content, and I will run everything past you. We are going forward either way, but I want to give you the opportunity if you are interested.

Id., Ex. C.

Augustine wanted to "teach the world" about his Bair Hugger theories, and worked with Plaintiffs' counsel to send his litigation guide to attorneys throughout the United States. *See* Augustine Dep. at 111:11-24 (admitting his goal to "teach the world about this problem" and "if it's a plaintiff's lawyer, that would work too"), 122:23-123:18 (discussing various responses and inquiries from attorneys regarding the litigation guide) (Davies Decl., Ex. D).

Since then, Augustine has made his team available to assist Plaintiffs' counsel with the litigation "in any way they can" and has gone so far as to ghostwrite certain materials for the lawyers. *Id.* at 124:6-19, 126:15-130:12, Ex. 20-21 (discussing Augustine's assistance in preparing counsel to take the depositions of 3M witnesses). In addition to furthering his vendetta against 3M, Augustine is using the litigation to further his business and financial interests. Augustine Dep. at 131:13-132:11 (admitting that when a new case is filed, Augustine's team tries to identify the hospital and medical personnel involved, and sends in his sales team to use the fact of the litigation to try and convince the hospitals to switch from the Bair Hugger to the HotDog). Augustine admits to using the fact of the litigation (which he personally designed and encouraged) to instill fear in these doctors and hospitals by suggesting they were likely to get sued next. *See id.* at 132:24-134:6. He has also repeated his claims in an "Executive Summary" accompanying a private placement

memorandum (through which he is soliciting investment in his HotDog system), suggesting that forced-air warming is at its "tipping point" and likely to be removed from the market. *See* Davies Decl., Ex. E at 2-3.

B. Augustine is Behind Many of the Studies he Claims as Support for His (and Plaintiffs') Theories.

Several of the documents at issue in this motion relate to studies sponsored and designed by Augustine in an (unsuccessful) effort to support his theory that the Bair Hugger system blows contaminated air into surgical wounds. These documents include including photos and other data underlying videos he produced and made publicly available via YouTube. *See* Ex. A. Augustine acknowledges that he has spoken at many conferences and written many articles for public consumption, in which he describes (1) particles he claims to have counted coming out of the Bair Hugger, and (2) bacteria allegedly scraped from inside of the Bair Hugger. Augustine has never disclosed, however, *that he repeatedly tried and failed* to capture live bacteria coming out of the Bair Hugger airstream. *See* Davies Decl., Ex. D at 71:16-72:16. In other words, he has repeatedly publicized data he believes helpful to his anti-Bair Hugger campaign, but wants to hide the information that undermines his claims.

Augustine also acknowledges his connection with Dr. Paul McGovern, who authored the 2011 study at the heart of Plaintiffs' case. Indeed, Augustine acknowledges that he has suggested McGovern publish a second article "to clear up the confusion" caused by his 2011 study. *See id.* at 24:15-26:19. Presumably, Augustine is concerned about the fact that the 2011 McGovern study identifies several factors contributing to the reduced

of this antibiotic change when, in fact, it had no affect at all"). According to Augustine, all McGovern has to do "is rerun the statistics, publish another article that clears that up, and it would be a great service to human kind." *Id.* at 26:19-22. There is no indication that McGovern agrees.

In addition, Augustine has publicly touted an FDA Medwatch report submitted by Dr. Robert Gauthier, which ostensibly supports Augustine's theory that the Bair Hugger system increases risk of surgical site infection. Augustine, however, admits that he wrote the report – not Dr. Gauthier – with the hope it would cause the FDA to take action. See id. at 160:23-163:5, Ex. 29. His plan failed. No regulator has ever suggested that the Bair Hugger presents any increased risk of surgical site infections, nor required adverse event reports to be filed. Most recently, there are documents relating to the email blast initiated by Augustine (or Augustine-controlled entities) in early 2017. These were sent to 3M customers and potential customers across the United States falsely claiming that the Bair Hugger system was being recalled and encouraging them to use Augustine's HotDog product instead. See Davies Decl., Ex. F. These documents obviously cannot be confidential, when they were publicly sent to countless 3M customers and potential customers throughout the United States. The above examples underscore how misguided Augustine's "confidential" designations really are.

<u>ARGUMENT</u>

In order to qualify for confidential treatment under the Protective Order and Rule 26(c), the information and documents to be protected must fall into one of the following

categories: (1) trade secret information; (2) proprietary confidential information or commercially or competitively sensitive information; (3) non-public marketing information; (4) non-public detailed sales and financial data; (5) customer lists; (6) nonpubic technical information; or (7) other non-public information of competitive, financial, or commercial significance comparable to the foregoing categories. See Protective Order, Doc. No. 39 at ¶ 2; Fed. R. Civ. P. 26(c). Information that has been disclosed or otherwise made available to the public will not be afforded confidential treatment. See id.; see also Order, ECF No. 500 at 2 (granting motion to de-designate "confidential" documents that had been made available to the public). The burden is on the party seeking protection to show that these requirements are met, and "[e]ach party or non-party that designates information or items for protection under this Order must take care to limit any such designation to specific material that, in good faith, qualifies under the appropriate standards." See id. at ¶¶ 4, 9 ("The party asserting that the material is Confidential shall have the burden of proving that the information in question is within the scope of protection afforded by Fed. R. Civ. P. 26(c)."); Order, ECF No. 500 at 3 (the party seeking protection has the burden of showing, as to each document, that it "has been previously maintained in a confidential manner" and "should be protected from disclosure and use outside the litigation because its disclosure and use is restricted by statute or could potentially cause harm to [its] interests").

Here, Augustine fails to articulate any good faith basis for the "confidential" designation placed on the documents produced to Defendants. His concern that 3M might use the documents or information outside of the context of this litigation does not justify

the confidential designation. The documents at issue do not fall into any category described in the Protective Order or Rule 26(c), and the "confidential" designation should not be permitted to stand.

Moreover, all of these documents either explicitly or implicitly refer to information already disclosed to the public through Augustine's litigation guide, his YouTube videos and public presentations, and other publicity he has generated (and attempted to generate) regarding his misguided theories about the Bair Hugger system.

The level to which this information has already been made available to third parties and/or the public is reason alone to lift the "confidential" designation. *See* Protective Order at ¶ 2 ("Information or documents that are available to the public may not be designated as Confidential Information."); see also In re Chrysler Motors Corp. Overnight Evaluation Program Litig., 860 F.2d 844 (8th Cir. 1988) (work product confidentiality waived where information was disclosed to third party, even where information was ultimately used by parties and for purposes other than what was intended at the time of initial disclosure).

Finally, the public interest favors lifting the designation. Augustine has falsely represented to the public that the use of forced-air warming may increase airborne contamination in operating rooms and the risk of infection. He has gone so far as to publish papers – or attempt to publish papers – under the names of other authors, in an effort to have the articles taken more seriously. In other words, Augustine is happy to have the substance of the articles made public, but wants to hide the fact that he wrote them.

Plaintiffs' counsel may attempt to disavow any involvement with Augustine (though it would be difficult for Kennedy Hodges), but they cannot deny that their case is based on

the same "facts" and theories that Augustine has made it his mission to create and pursue. Neither Augustine nor Plaintiffs should be permitted to continue to mislead the public with half-truths about the Bair Hugger system or the imagined benefits of using Augustine's HotDog product.

CONCLUSION

For all of the foregoing reasons, Defendants respectfully request that the "confidential" designation be lifted from the Augustine Documents.

Dated: June 5, 2017 Respectfully submitted,

/s/ Monica L. Davies

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